

OFIS is currently accepting comments from any interested person regarding Blue Cross Blue Shield of Michigan's (BCBSM's) filing of Rider BMT, (Bone Marrow Transplant), Form No. 4398; Rider SOCT (Specified Oncology Clinical Trails), Form No. 5401; and Rider EBMT (Experimental Bone Marrow Transplant), Form No. 4397. Riders BMT, SOCT, & EBMT currently exist and would be revised with this filing.

Comments on the revisions of Riders BMT, SOCT, & EBMT shall be accepted by e-mail, fax or in the form of written testimony through **March 18, 2002**. All comments must be received by 5:00 p.m. on **March 18, 2002**, in order for it to be considered as part of the Commissioner's review of the proposed revisions. Comments provided by e-mail should be directed to dscochr@michigan.gov. Written comments can be mailed or faxed to:

Office of Financial and Insurance Services
Attention: Debra S. Cochran
P. O. Box 30220
Lansing, MI 48909
Fax: (517) 241-4168



State of Michigan
John Engler, Governor

Department of Consumer & Industry Services
Kathleen M. Wilbur, Director

Office of Financial and Insurance Services
Frank M. Fitzgerald, Commissioner

P.O. Box 30220
Lansing, MI 48909-7720
Toll Free (877) 999-6442
Lansing Area (517) 373-0220
Web site: www.cis.state.mi.us/ofis/

March 1, 2002

MEMORANDUM

To: Health Care Providers, BCBSM Subscribers, Interest Groups,
and Other Interested Persons

From: Debra S. Cochran, Departmental Specialist
Health Plans Division

Subject: Rider BMT, (Bone Marrow Transplant), Form No. 4398
Rider SOCT (Specified Oncology Clinical Trails), Form No. 5401
Rider EBMT (Experimental Bone Marrow Transplant), Form No. 4397

On February 25, 2002, Blue Cross and Blue Shield of Michigan (BCBSM) filed with the Office of Financial and Insurance Services (OFIS), as required under MCL 550.1607(1), revisions to Rider BMT, (Bone Marrow Transplant), Rider SOCT (Specified Oncology Clinical Trails), and Rider EBMT (Experimental Bone Marrow Transplant).

Riders BMT and SOCT amend all BCBSM group, nongroup and group conversion certificates. Rider EBMT amends BCBSM group benefit certificates. Rider BMT is mandatory for all underwritten individuals and groups. Rider SOCT is mandatory for groups and individuals who do not have Rider EBMT. Rider EBMT is available to experience rated groups only.

In their filing letter, BCBSM summarized the proposed changes for Rider BMT, Rider SOCT, and Rider EBMT as follows:

"Rider BMT has been revised to expand the diagnoses for which allogeneic and autologous hematopoietic transplants will be covered; however, coverage for high dose chemotherapy with transplant to treat stage IV breast cancer has been moved to Rider SOCT. In addition, the following changes have been made:

- Title is changed to hematopoietic stem cell transplant to reflect that more than bone marrow transplants are covered.

- Recognizes coverage for umbilical cord blood harvesting, storage and transplant under the benefit for allogeneic transplants.
- Recognizes coverage for t-cell depleted infusion and donor lymphocyte infusion under the benefit for allogeneic transplants.
- Recognizes coverage for tandem transplants when performed to treat germ cell tumors of the testes.
- Adds exclusion of routine harvesting and storage of umbilical cord blood for possible use at some unspecified time in the future.
- Adds exclusion of more than two tandem transplants, two single transplants or a single and tandem transplant per member for the same condition.
- Adds a cross reference to Rider GLE-1 to ensure members understand that routine services rendered as part of a clinical trial may be covered.
- Miscellaneous updates to language to make it consistent with other riders.

Rider SOCT has been revised in the following ways:

- Includes coverage of high dose chemotherapy with transplant to treat stage IV breast cancer if rendered as part of an approved clinical trial.
- Eliminates requirement that clinical trials meet ASCO guidelines because such guidelines are no longer applicable.
- Eliminates coverage for allogeneic transplants because the medical community has not, and does not, perform such transplants to treat stages II, III and IV breast cancer and all stages of ovarian cancer.
- Eliminates requirement that transplants be performed within one year.
- Adds exclusion of more than two single transplants per member per condition.
- Adds a cross reference to Rider GLE-1 to ensure members understand that routine services rendered as part of a clinical trial may be covered.
- Miscellaneous updates to language to make it consistent with other riders.

Memorandum
March 1, 2002
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Rider EBMT has been revised to include updated language to make it consistent with other riders and to include a cross reference to Rider GLE-1 to ensure members understand that routine services rendered as part of a clinical trial may be covered."

These riders are not new. BCBSM is now proposing changes to these riders. Any action the Commissioner takes on this filing must be within 30 days after the filing.

A public hearing was held on May 14, 1996 to elicit comment on benefit exclusions for experimental or investigational medical treatments. This hearing was held in large part, to receive comments on a previous version of these riders.

The Commissioner is now asking for comments on the proposed changes before he acts on the filing.

A copy of BCBSM's revisions to Rider BMT, (Bone Marrow Transplant), Rider SOCT (Specified Oncology Clinical Trails), and Rider EBMT (Experimental Bone Marrow Transplant) are available on OFIS' website at www.cis.state.mi.us/ofis. If you desire a printed copy of the filing, you may request one from Debra Cochran at (517) 335-2059.

Comments on BCBSM's revisions to Rider BMT, (Bone Marrow Transplant), Rider SOCT (Specified Oncology Clinical Trails), and Rider EBMT (Experimental Bone Marrow Transplant) shall be accepted by e-mail, fax or in the form of written comments through **March 18, 2002**. All comments must be received by **5:00 p.m. on March 18, 2002** in order for it to be considered as part of the Commissioner's review. Comments provided by e-mail should be directed to dscochr@michigan.gov. Written comments can be mailed or faxed to:

Office of Financial and Insurance Services
Attention: Debra S. Cochran
P. O. Box 30220
Lansing, MI 48909
Fax: (517) 241-4168

At the conclusion of the comment period, the Commissioner will consider all of the comments and the information and establish if the benefit meets the requirements under MCL 550.1607. The Commissioner is expected to act on this filing by March 27, 2002.

If you have any questions regarding the comment process, you may contact me at (517) 335-2059.

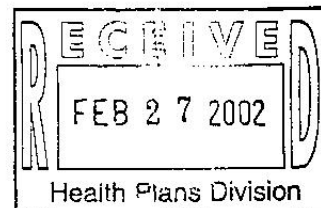


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Robert W. Kasperek
Vice President and
Deputy General Counsel
Regulatory Affairs

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Detroit, Michigan 48226-2998
Telephone: (313) 225-8135
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February 22, 2002



Ms. Joan Moiles
Director, Health Plans Division
Office of Policy and Consumer Services
611 West Ottawa Street
Lansing, MI 48933

Re: Rider BMT Form No. 4398 (Bone Marrow Transplant)
Rider SOCT Form No. 5401 (Specified Oncology
Clinical Trials)
Rider EBMT Form No. 4397 (Experimental Bone Marrow
Transplant)

Dear Ms. Moiles:

Enclosed are two copies of the above referenced riders and an additional copy of the cover letter. In accordance with the Office of Financial and Insurance Services' suggested procedure for form filings, the following information is hereby provided:

1. REQUEST FOR ACTION

The above referenced riders are being filed for the Office of Financial and Insurance Services review and approval.

2. PURPOSE AND USE

Riders BMT and SOCT amend all BCBSM group, nongroup and group conversion certificates. Rider EBMT amends BCBSM group benefit certificates. Rider BMT is mandatory for all underwritten individuals and groups. Rider SOCT is mandatory for groups and individuals who do not have Rider EBMT. Rider EBMT is available to experience-rated groups only.

3. DISPOSITION OF CURRENT FORMS

These riders currently exist but have been revised. The names and form numbers will not change.

4. PROPOSED IMPLEMENTATION DATE

Riders BMT, SOCT and EBMT will be implemented as soon as administratively possible.

5. APPLICATION CARD

6. IDENTIFICATION CARD

The application and identification cards for the forms are the same as those currently in use and on file with the Office of Financial and Insurance Services.

7. LANGUAGE CERTIFICATION

I certify, to the best of my knowledge and belief, that the forms clearly describe the benefits, exclusions and limitations, and that the language was written to be understandable to a layperson.

8. PROVIDERS CERTIFICATION

I certify, to the best of my knowledge and belief, the benefits being proposed are to be provided by, or ordered by, health care providers or professionals specifically indicated in Public Act of 1980.

9. BENEFITS, EXCLUSIONS AND LIMITATIONS

Rider BMT has been revised to expand the diagnoses for which allogeneic and autologous hematopoietic transplants will be covered; however, coverage for high dose chemotherapy with transplant to treat stage IV breast cancer has been moved to Rider SOCT. In addition, the following changes have been made:

- Title is changed to hematopoietic stem cell transplant to reflect that more than bone marrow transplants are covered.
- Recognizes coverage for umbilical cord blood harvesting, storage and transplant under the benefit for allogeneic transplants.
- Recognizes coverage for t-cell depleted infusion and donor lymphocyte infusion under the benefit for allogeneic transplants.

- Recognizes coverage for tandem transplants when performed to treat germ cell tumors of the testes.
- Adds exclusion of routine harvesting and storage of umbilical cord blood for possible use at some unspecified time in the future.
- Adds exclusion of more than two tandem transplants, two single transplants or a single and tandem transplant per member for the same condition.
- Adds a cross reference to Rider GLE-1 to ensure members understand that routine services rendered as part of a clinical trial may be covered.
- Miscellaneous updates to language to make it consistent with other riders.

Rider SOCT has been revised in the following ways:

- Includes coverage of high dose chemotherapy with transplant to treat stage IV breast cancer if rendered as part of an approved clinical trial.
- Eliminates requirement that clinical trials meet ASCO guidelines because such guidelines are no longer applicable.
- Eliminates coverage for allogeneic transplants because the medical community has not, and does not, perform such transplants to treat stages II, III and IV breast cancer and all stages of ovarian cancer.
- Eliminates requirement that transplants be performed within one year.
- Adds exclusion of more than two single transplants per member per condition.
- Adds a cross reference to Rider GLE-1 to ensure members understand that routine services rendered as part of a clinical trial may be covered.

- Miscellaneous updates to language to make it consistent with other riders.

Rider EBMT has been revised to include updated language to make it consistent with other riders and to include a cross reference to Rider GLE-1 to ensure members understand that routine services rendered as part of a clinical trial may be covered.

10. **COMPLIANCE CERTIFICATION**
11. **PRIOR DENIAL CERTIFICATION**

I certify, to the best of my knowledge and belief, the riders are in compliance with all applicable Michigan laws and do not contain provisions previously disapproved by the bureau or identified as requiring correction or revision.

12. **LANGUAGE CHANGES INDEX**

The forms are not new; these are revisions of forms currently on file with the bureau.

13. **RATE SCHEDULE AND RATIONALE**
14. **ACTUARIAL CERTIFICATION**

Riders BMT and SOCT continue to be non-rated. The rates for Rider EBMT are on file with OFIS and have not been impacted by the revisions.

Sincerely,



Robert W. Kasperek

RWK/LV/rlw

Enclosures

IMPORTANT

FINAL

Keep This Rider With Your Certificate

**Rider BMT
HEMATOPOIETIC STEM CELL TRANSPLANT
AMENDS**

**ALL BCBSM GROUP, NONGROUP and
GROUP CONVERSION BENEFIT CERTIFICATES
(excluding Dental Care, Vision Care, and
Prescription Drug Program certificates)**

Rider BMT amends the certificates named above to clarify the conditions for which hematopoietic (bone marrow, peripheral blood stem cell or umbilical cord blood) transplants and tandem transplants for germ cell tumors of the testes are payable.

This rider is effective when you, your employer or remitting agent is notified.

Your certificate is amended as follows:

SECTION 1: DEFINITIONS

Allogeneic (Allogenic) Transplant

A procedure using another person's bone marrow, peripheral blood stem cells or umbilical cord blood to transplant into the patient. This includes syngeneic transplants.

Autologous Transplant

A procedure using the patient's own bone marrow or peripheral blood stem cells to transplant back into the patient.

Colony Stimulating Growth Factors

Factors that stimulate the multiplication of very young blood cells.

First Degree Relative

An immediate family member; that is, a mother, father, sister or brother.

Hematopoietic Stem Cell Transplant

A transplant of bone marrow, peripheral blood stem cells or umbilical cord blood.

High Dose Chemotherapy

A procedure in which patients are given cell destroying drugs in doses higher than those used in conventional therapy. Stem cell replacement is required after HDC is given.

HLA Genetic Markers

Specific chemical groupings that are part of many body cells, including white blood cells. Called human leukocyte antigens, these chemical groupings are inherited from each parent and are used to detect the constitutional similarity of one person to another. Close (or the degree of) identity is determined by tests using serologic (test tube) methods and/or molecular (DNA fingerprinting) techniques. A complete HLA match occurs when the six clinically important markers of the donor are identical to those of the patient.

Peripheral Blood Stem Cell Transplant

A procedure where blood stem cells are obtained by pheresis and infused into the patient's circulation.

Pheresis

Removal of blood from the donor or patient in order to separate and retain specific components of the blood (red cells, white cells, platelets, and stem cells).

Purging

A process that attempts to remove abnormal cells from a blood or bone marrow sample so that a clean sample with only normal blood producing cells is obtained.

SECTION 1: DEFINITIONS (continued)

Refractory Patient

An individual who does not achieve clinical disappearance of the disease after standard therapy.

Relapse

When a disease recurs after a period of time following therapy. This period of time is defined by evidence-based literature pertaining to the patient's condition.

Service

Surgery, care, treatment, supplies, devices, drugs or equipment given by a health care provider to diagnose or treat a disease or condition.

Stem Cells

Primitive blood cells originating in the marrow but also found in small quantities in the blood. These cells develop into mature blood elements including red cells, white cells and platelets.

Syngeneic Transplant

A procedure using bone marrow, peripheral blood stem cells or umbilical cord blood from a patient's identical twin to transplant into the patient.

Tandem Transplant

A procedure in which the patient is given high dose chemotherapy and then an autologous blood stem cell or bone marrow transplant, followed within three to six months by a second round of high dose chemotherapy and another peripheral blood stem cell or bone marrow transplant.

Total Body Irradiation

A procedure that exposes most of the body to ionizing radiation to produce an anti-tumor effect that helps prevent rejection of a bone marrow, umbilical cord blood or peripheral blood stem cell transplant.

SECTION 2: Services That Are Payable

The services covered in your basic certificate(s) and rider(s) are payable when directly related to a transplant covered under this rider.

We pay for the following services:

Allogeneic Transplants

- blood tests on first degree relatives to evaluate them as donors (if the tests are not covered by their insurance)
- search of the National Bone Marrow Donor Program Registry for a donor. A search will begin only when the need for a donor is established.

SECTION 2: Services That Are Payable (continued)

- infusion of colony stimulating growth factors.
- harvesting (including peripheral blood stem cell pheresis) and storage of the donor's bone marrow, peripheral blood stem cell and/or umbilical cord blood, if the donor is:
 - a first degree relative and matches at least four of the six important HLA genetic markers with the patient; or
 - not a first degree relative and matches five of the six important HLA genetic markers with the patient. (This provision does not apply to transplants for sickle cell anemia, (ss or sc) or beta thalassemia)

NOTES:

- harvesting and storage will be covered by us even if it is not covered by the donor's insurance.
- in a case of sickle cell anemia, (ss or sc) or beta thalassemia, the donor must be an HLA-identical sibling.
- high dose chemotherapy and/or total body irradiation.
- infusion of bone marrow, peripheral blood stem cells, and/or umbilical cord blood.
- t-cell depleted infusion
- donor lymphocyte infusion
- hospitalization

• Autologous Transplants

- infusion of colony stimulating growth factors

- harvesting (including peripheral blood stem cell pheresis) and storage of bone marrow and/or peripheral blood stem cells.
- purging or positive stem cell selection of bone marrow or peripheral blood stem cells
- high dose chemotherapy and/or total body irradiation.
- infusion of bone marrow and/or peripheral blood stem cells.

SECTION 2: Services That Are Payable (continued)

- hospitalization.

NOTE: A tandem transplant is covered only when it treats germ cell tumors of the testes.

SECTION 3: Conditions for Which Transplants are Payable

- Allogeneic transplants are covered to treat:
 - Acute lymphocytic leukemia (high risk, refractory or relapsed patients)
 - Acute non-lymphocytic leukemia (high risk, refractory or relapsed patients)
 - Aplastic anemia
 - Beta Thalassemia
 - Chronic myeloid leukemia
 - Hodgkin's disease (high risk, refractory or relapsed patients)
 - Myelodysplastic syndromes
 - Neuroblastoma (stage III or IV)
 - Non-Hodgkin's lymphoma (high risk, refractory or relapsed patients)
 - Osteopetrosis
 - Severe combined immune deficiency disease
 - Wiskott-Aldrich syndrome
 - Sickle Cell Anemia (ss or sc)
 - Myelofibrosis
 - Multiple myeloma
 - Primary amyloidosis (AL)
 - Glanzmann thrombasthenia
 - Paroxysmal nocturnal hemoglobinuria
 - Kostmann's syndrome
 - Leukocyte adhesion deficiencies
 - X-linked lymphoproliferative syndrome
 - Megakaryocytic thrombocytopenia
 - Mantle cell lymphoma
 - Congenital leukocyte dysfunction syndromes

- Congenital pure red cell aplasia
- Chronic lymphocytic leukemia
- Mucopolysaccharidoses (e.g., Hunter's, Hurler's, Sanfilippo, Maroteaux-Lamy variants) in patients who are neurologically intact
- Mucopolipidoses (e.g., Gaucher's disease, metachromatic leukodystrophy, globoid cell leukodystrophy, adrenoleukodystrophy) for patients who have failed conventional therapy (e.g., diet, enzyme replacement) and who are neurologically intact)

- **Autologous transplants are covered to treat:**

- Acute lymphocytic leukemia (high risk, refractory or relapsed patients)

SECTION 3: Conditions for Which Transplants are Payable (continued)

- Acute non-lymphocytic leukemia (high risk, refractory or relapsed patients)
- Germ cell tumors of ovary, testis, mediastinum, retroperitoneum
- Hodgkin's disease (high risk, refractory or relapsed patients)
- Neuroblastoma (stage III or IV)
- Non-Hodgkin's lymphoma (high risk, refractory or relapsed patients)
- Multiple myeloma
- Primitive neuroectodermal tumors
- Ewing's sarcoma
- Medulloblastoma
- Wilms' Tumor
- Primary amyloidosis (AL)
- Rhabdomyosarcoma
- Mantle cell lymphoma

NOTE: In addition to the conditions listed above, we will pay the services related to, or for high dose chemotherapy, total body irradiation, allogeneic or autologous transplants to treat conditions that are not experimental or investigational. This rider does not limit or preclude coverage of antineoplastic drugs when Michigan law requires that these drugs, and the reasonable cost of their administration, be covered.

SECTION 4: Limitations and Exclusions

In addition to the limitations and exclusions listed in your certificate(s) and rider(s), we do not pay for:

- services that are not medically necessary (see your certificate for the definition of medically necessary).

- services provided by persons or entities that are not legally qualified or licensed to provide such services.
- services rendered to a donor when the donor's health care coverage will pay for such services.
- any services related to, or for, allogeneic transplants when the donor does not meet the HLA genetic marker matching requirements.
- a tandem transplant for any condition other than germ cell tumors of the testes.
- more than two tandem transplants, two single transplants or a single and tandem transplant per member for the same condition.

SECTION 4: Limitations and Exclusions (continued)

- the routine harvesting and storage of a newborn's umbilical cord blood for possible use at some unspecified time in the future.
- any other services, admissions or length of stay related to any of the above named exclusions.

The lifetime maximum, if any, in your underlying certificate(s) applies to the services under this rider.

GENERAL

Until further notice, all the terms, definitions, limitations, exclusions and conditions, of your certificate and related riders remain unchanged and in full force and effect, except as otherwise provided in Rider BMT.

BLUE CROSS BLUE SHIELD OF MICHIGAN

**Richard E. Whitmer
President and Chief Executive Officer**

11/13/01

IMPORTANT

KEEP THIS RIDER WITH YOUR CERTIFICATE

RIDER SOCT SPECIFIED ONCOLOGY CLINICAL TRIALS

AMENDS

**ALL BCBSM GROUP, NONGROUP AND GROUP CONVERSION
CERTIFICATES
(excluding Medicare Supplemental, Dental Care,
Vision Care and Prescription Drug certificates)**

Rider SOCT amends the certificates named above to provide coverage for preapproved, specified bone marrow and/or peripheral blood stem cell transplants and related services to treat stages II, III and IV breast cancer and/or all stages of ovarian cancer during an approved clinical trial.

This rider is effective when you, your employer or remitting agent is notified.



An Independent Licensee of the Blue Cross and Blue Shield Association

Your certificate is amended as follows:

SECTION 1: Definitions

Affiliate Cancer Center

A health care provider that has contracted with an NCI-approved cancer center to provide treatment.

Autologous Transplant

A procedure using the patient's own bone marrow or peripheral blood stem cells to transplant back into the patient.

Clinical Trial

A study conducted on a group of patients to determine the effect of a treatment. For purposes of this rider, clinical trials include:

- Phase II - a study conducted on a number of patients to determine whether the treatment has a positive effect on the disease or condition as compared to the side effects of the treatment.
- Phase III - a study conducted on a much larger group of patients to compare the results of a new treatment of a condition to the results of conventional or standard treatment. Phase III gives an indication as to whether the new treatment leads to better, worse or no change in outcome.

Colony Stimulating Growth Factors

Factors that stimulate the multiplication of very young blood cells.

Designated Cancer Center

A site approved by the National Cancer Institute as a cancer center, comprehensive cancer center, clinical cancer center or an affiliate of one of these centers. The names of the approved centers and their affiliates are available to you and your physician upon request.

High Dose Chemotherapy

A procedure in which patients are given cell destroying drugs in doses higher than those used in conventional therapy. Stem cell replacement is required after high dose chemotherapy is given.

SECTION 1: Definitions (continued)

Peripheral Blood Stem Cell Transplant

A procedure in which blood stem cells are obtained by pheresis and infused into the patient's circulation.

Pheresis

Removal of blood from the donor or patient in order to separate and retain specific components of the blood (red cells, white cells, platelets and stem cells).

Purging

A process that attempts to remove abnormal cells from a blood or bone marrow sample so that a clean sample with only normal blood producing cells is obtained.

Service

Surgery, care, treatment, supplies, devices, drugs or equipment given by a health care provider to diagnose or treat a disease or condition.

Stem Cells

Primitive blood cells originating in the marrow but also found in small quantities in the blood. These cells develop into mature blood components including red cells, white cells and platelets.

Total Body Irradiation

A procedure that exposes most of the body to ionizing radiation to produce an anti-tumor effect that helps prevent rejection of a bone marrow or peripheral blood stem cell transplant.

SECTION 2: Coverage Under This Rider

Rider SOCT covers bone marrow and peripheral blood stem cell transplants, their related services and FDA-approved antineoplastic drugs to treat stages II, III and IV breast cancer and all stages of ovarian cancer when they are provided pursuant to an approved phase II or III clinical trial. This rider does not limit or preclude coverage of antineoplastic drugs when Michigan law requires that these drugs, and the reasonable cost of their administration, be covered.

SECTION 3: Mandatory Preapproval

We will not pay benefits under this rider for services, admissions or lengths of stay that are not preapproved.

The preapproval process allows you and your provider to know if we will cover proposed services, hospital admissions and lengths of stay in a hospital before treatment begins. If preapproval is not obtained **before** you receive services or are admitted to a hospital, the services, admission and length of stay will not be covered under this rider.

NOTE: Preapproval is good only for one year after it is issued. However, preapproved services, admissions or lengths of stay will not be paid if you no longer have coverage under this rider at the time they occur.

A decision to preapprove services, an admission or length of stay will be based on the information your provider submits to us. BCBSM reserves the right to request other information to determine if preapproval is appropriate.

If your condition or proposed treatment plan changes after preapproval is granted, your provider must submit a new request for preapproval. Failure to do so will result in the transplant, related services, admission and length of stay not being covered.

The designated cancer center must submit its written request for preapproval to:

Blue Cross Blue Shield of Michigan
Human Organ Transplant Program
Mail Code J607
600 Lafayette East
Detroit, MI 48226
Fax: (313) 225-5827

Preapproval will be granted if:

- the patient is an eligible BCBSM member
- the patient has BCBSM hospital-medical-surgical coverage
- the proposed services will be rendered in a designated cancer center or in an affiliate of a designated center

SECTION 3: Mandatory Preapproval (continued)

- the proposed services are medically necessary
- an inpatient admission to a hospital and the length of stay at the hospital are medically necessary (in those cases requiring inpatient hospital treatment). A request for an admission and length of stay must be preapproved by BCBSM before the admission occurs.

SECTION 4: Services That Are Payable

The services covered in your basic certificate(s) and rider(s) are payable when directly related to a transplant covered under this rider. **The transplant must be performed at a designated cancer center or its affiliate to be a covered benefit under this rider.**

We pay for the following only after they have been preapproved by BCBSM:

- **Autologous Transplants**
 - Infusion of colony stimulating growth factors
 - Harvesting (including peripheral blood stem cell phereses) and storage of bone marrow and/or peripheral blood stem cells
 - Purging or positive stem cell selection of bone marrow or blood stem cells
 - High dose chemotherapy and/or total body irradiation
 - Infusion of bone marrow and/or peripheral blood stem cells
 - Hospitalization

SECTION 5: Travel, Meals and Lodging

We will pay up to a total of \$5,000 for travel, meals and lodging expenses directly related to preapproved services rendered during an approved clinical trial. The expenses must be incurred during the period that begins with the date of preapproval and ends 180 days after the transplant. However, these expenses will not be paid if your coverage under this rider is no longer in effect.

SECTION 5: Travel, Meals and Lodging (continued)

The allowance for travel, meals and lodging covers the expenses of an adult patient and another person, or expenses of a patient under the age of 18 years and two additional people. The following per-day amounts apply to the combined expenses of the patient and persons eligible to accompany the patient up to:

- \$60 per day for travel
- \$50 per day for lodging
- \$40 per day for meals

NOTE: These daily allowances may be adjusted periodically. Please contact BCBSM for the current maximums allowed.

SECTION 6: Limitations and Exclusions

In addition to the limitations and exclusions listed in your certificate(s) and rider(s), we do not pay for:

- A hospital admission or a length of stay at a hospital that has not been preapproved
- Services that have not been preapproved
- Services that are not medically necessary (see your certificate for the definition of medically necessary)
- Services provided by persons or entities that are not legally qualified or licensed to provide such services
- More than two single transplants per member for the same condition
- Items, such as investigational drugs, that are normally covered by other funding sources (e.g., investigational drugs funded by a drug company)
- Nonhealth care related services and/or research management (such as administrative costs).

- Transplants performed at a center that is not a designated cancer center or its affiliate

SECTION 6: Limitations and Exclusions (continued)

- Items that are not considered directly related to travel, meals and lodging expenses. They include, but are not limited to, dry cleaning, clothing, laundry services, kennel fees, entertainment (cable televisions, books, magazines, movie rentals), car maintenance, toiletries, security deposits, toys, household products, alcoholic beverages, flowers, cards, stationery, stamps, household utilities, including cell phone charges, maid, baby-sitter or day care services.
- Experimental and investigational services not included in this rider
- Any other services, admissions or lengths of stay related to any of the above exclusions

NOTE: Services not covered under this rider may be covered in your certificates and other riders. Please refer to Rider GLE-1 for additional information.

The lifetime maximum, copayments and deductible, if any, in your underlying certificate(s) apply to the services in this rider.

GENERAL

Until further notice, all the terms, definitions, limitations, exclusions and conditions of your certificate and related riders remain unchanged and in full force and effect, except as otherwise provided in Rider SOCT.

BLUE CROSS BLUE SHIELD OF MICHIGAN

Richard E. Whitmer
President and Chief Executive Officer

11/14/01
FINAL

IMPORTANT

KEEP THIS RIDER WITH YOUR CERTIFICATE

RIDER EBMT
EXPERIMENTAL BONE MARROW TRANSPLANT COVERAGE
AVAILABLE TO EXPERIENCE-RATED GROUPS ONLY

AMENDS

ALL BCBSM GROUP BENEFIT CERTIFICATES
(excluding Medicare Supplemental, Prescription Drug,
Dental and Vision certificates)

Rider EBMT amends the certificates named above to provide coverage for specific hematopoietic transplants and related services not otherwise covered under Rider BMT.

This rider is effective when you, your employer or remitting agent is notified.



An Independent Licensee of the Blue Cross and Blue Shield Association

Your certificate is amended as follows;

SECTION 1: Definitions

Allogeneic (Allogenic) Transplant

A procedure using another person's bone marrow, peripheral blood stem cells or umbilical cord blood to transplant into the patient. This includes syngeneic transplants.

Autologous Transplant

A procedure using the patient's own bone marrow or peripheral blood stem cells to transplant back into the patient.

Colony Stimulating Growth Factors

Factors that stimulate the multiplication of very young blood cells.

Hematopoietic Transplant

A transplant of bone marrow, peripheral blood stem cells or umbilical cord blood.

High Dose Chemotherapy

A procedure in which patients are given cell destroying drugs in doses higher than those used in conventional therapy. Stem cell replacement is required after high dose chemotherapy is given.

HLA Genetic Markers

Specific chemical groupings that are part of many body cells, including white blood cells. Called human leukocyte antigens, these chemical groupings are inherited from each parent and are used to detect the constitutional similarity of one person to another. Close (or the degree of) identity is determined by tests using serologic (test tube) methods and/or molecular (DNA fingerprinting) techniques. An HLA identical match occurs when the six clinically important markers of the donor are identical to those of the patient.

Peripheral Blood Stem Cell Transplant

A procedure in which blood stem cells are obtained by pheresis and infused into the patient's circulation.

Pheresis

Removal of blood from the donor or patient in order to separate and retain specific components of the blood (red cells, white cells, platelets and stem cells).

Purging

A process that attempts to remove abnormal cells from a blood or bone marrow sample so that a clean sample with only normal blood producing cells is obtained.

SECTION 1: Definitions (continued)

Services

Surgery, care, treatment, supplies, devices, drugs or equipment given by a health care provider to diagnose or treat a disease or condition.

Stem Cells

Primitive blood cells originating in the marrow but also found in small quantities in the blood. These cells develop into mature blood elements including red cells, white cells and platelets.

Syngeneic Transplant

A procedure using bone marrow, peripheral blood stem cells or umbilical cord blood from a patient's identical twin to transplant into the patient.

Tandem Transplant

A procedure in which the patient is given high dose chemotherapy and then a peripheral blood stem cell or bone marrow transplant, followed within three to six months by a second round of high dose chemotherapy and another peripheral blood stem cell or bone marrow transplant. For purposes of this rider, a tandem transplant is considered one transplant.

T-Cell Depleted Infusion

A procedure in which T-Cells (immunocompetent lymphocytes) are eliminated from peripheral blood stem cells, bone marrow or umbilical cord blood.

Total Body Irradiation

A procedure that exposes most of the body to ionizing radiation to produce an anti-tumor effect that helps prevent rejection of a bone marrow, peripheral blood stem cell or umbilical cord blood transplant.

SECTION 2: Coverage Under This Rider

Rider EBMT covers hematopoietic transplants and their related services and FDA approved antineoplastic drugs to treat the conditions listed in this rider. This rider does not limit or preclude coverage of antineoplastic drugs when Michigan law requires that these drugs, and the reasonable cost of their administration, be covered.

SECTION 3: Mandatory Preapproval

We will not pay benefits under this rider for services, admissions or lengths of stay that are not preapproved .

The preapproval process allows you and your provider to know if we will cover proposed services, hospital admissions and lengths of stay in a hospital before treatment begins. If preapproval is not obtained before you receive services or are admitted to a hospital, the services, admission and lengths of stay will not be covered under this rider.

NOTE: Preapproval is good only for one year after it is issued. However, preapproved services, admissions or lengths of stay will not be paid if you no longer have coverage under this rider at the time they occur.

A decision to preapprove services, an admission or length of stay will be based on the information your provider submits to us. BCBSM reserves the right to request other information to determine if preapproval is appropriate.

If your condition or proposed treatment plan changes after preapproval is granted, your provider must submit a new request for preapproval. Failure to do so will result in the transplant, related services, admission and length of stay not being covered.

Your provider must submit its written request for preapproval to:

Blue Cross Blue Shield of Michigan
Human Organ Transplant Program
Mail Code J607
600 Lafayette East
Detroit, MI 48226
Fax: (313) 225-5827

Preapproval will be granted if:

- the patient is an eligible BCBSM member
- the patient has BCBSM hospital-medical-surgical coverage
- the proposed services are medically necessary

SECTION 3: Mandatory Preapproval (continued)

- an inpatient admission to a hospital and the length of stay at the hospital are medically necessary (in those cases requiring inpatient hospital treatment). A request for an admission and length of stay must be preapproved by BCBSM before the admission occurs.

SECTION 4: Services That Are Payable

The services covered in your basic certificate(s) and rider(s) are payable when directly related to transplants covered in this rider.

We pay for the following only after they have been preapproved by BCBSM:

- Blood tests to evaluate donors (if not covered by the potential donor's insurance)
- Search of the National Marrow Donor Program Registry for a donor. A search will begin only when the need for a donor is established.
- Infusion of colony stimulating growth factors
- Harvesting (including peripheral blood stem cell pheresis) and storage of the donor's bone marrow, peripheral blood stem cells and/or umbilical cord blood
- Purging or positive stem cell selection of bone marrow or peripheral blood stem cells for autologous transplants
- High dose chemotherapy and/or total body irradiation
- Infusion of bone marrow, peripheral blood stem cells and/or umbilical cord blood
- T-cell depleted infusion for allogeneic transplantation
- Hospitalization
- Services you receive as a donor of bone marrow and/or peripheral blood stem cells (e.g., infusion of growth stimulating factors, hospitalization, blood tests and harvesting, as detailed above)

SECTION 4: Services That Are Payable (continued)

The above services are payable for autologous and allogeneic transplants if they treat certain solid tumors involving:

- Breast (stage I, II, III and IV)
- Colon
- Lung
- Brain
- Skin
- Epithelium
- Prostate
- Stomach
- Kidney
- Uterus
- Cervix

- The above services are also payable for allogeneic transplants from non-identical HLA donors when they treat the following conditions:

- Aplastic anemia
- Acute lymphocytic leukemia
- Acute nonlymphocytic leukemia
- Chronic myeloid leukemia
- Severe combined immune deficiency disease
- Wiskott-Aldrich syndrome
- Osteopetrosis
- Beta thalassemia, major
- Neuroblastoma (Stage III or IV)
- Non-Hodgkin's Lymphoma (Intermediate or High grade)
- Multiple myeloma (This condition is also payable when the donor is HLA identical.)

NOTE: Allogeneic transplants are considered experimental when an unrelated donor has more than one HLA genetic marker mismatch, and related donors have more than two HLA genetic marker mismatches.

SECTION 5: Limitations and Exclusions

In addition to the limitations and exclusions listed in your certificate(s) and rider(s), we do not pay for the following:

- A hospital admission or length of stay at a hospital that has not been preapproved
- Services that have not been preapproved

SECTION 5: Limitation and Exclusions (continued)

- Services that are not medically necessary (see your certificate for a definition of medically necessary)
- A transplant intended to treat a condition not described in this rider
- Services provided by persons or entities that are not legally qualified or licensed to provide such services
- Donor services intended to treat a condition not described in this rider
- Services rendered to a donor when the donor's health care coverage will pay for such services
- More than two tandem transplants, two single transplants or a single and a tandem transplant per member for the same condition
- Items, such as investigational drugs, that are normally covered by other funding sources (e.g., investigational drugs funded by a drug company)
- Nonhealth care services and/or research management (such as administrative costs)
- Services not included in this rider
- Treatment of a condition not covered in this rider
- Any other services, admissions or lengths of stay related to any of the above exclusions

NOTE: Services not covered under this rider may be covered in your certificates and other riders. Please refer to Rider GLE-1 for additional information.

The lifetime maximum, copayments and deductibles, if any, in your underlying certificate(s) apply to the services in this rider.

GENERAL

Until further notice, all the terms, definitions, limitations, exclusions and conditions, of your certificate and related riders remain unchanged and in full force and effect, except as otherwise provided in Rider EBMT.

BLUE CROSS BLUE SHIELD OF MICHIGAN

Richard E. Whitmer
President and Chief Executive Officer

Form No. 4397